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E-1950

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7590

09/11/2009

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EXAMINER

PURDY, KYLE A

ART UNIT

PAPER NUMBER

1611

MAIL DATE

DELIVERY MODE

09/11/2009

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 09/754,010	<b>Applicant(s)</b> DILLON, MARK E.	
	<b>Examiner</b> Kyle Purdy	<b>Art Unit</b> 1611	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 01 June 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 34-54 is/are pending in the application.
- 4a) Of the above claim(s) 46-54 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 34-45 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Status of Application***

1. The Examiner acknowledges receipt of the amendments filed on 06/01/2009 wherein claims 34 has been amended.
2. Claims 34-45 are presented for examination on the merits. The following rejections are made.

### ***Claim Objections***

3. Claim 41 is objected to because of the following informalities: not properly identifying changes made to the claim. Claim 41 is presently listed as 'currently amended', however, no addition or deletion has been indicated in the body of the claim. Appropriate correction is required.

### ***Response to Applicants' Arguments***

4. Applicants arguments filed 06/01/2009 regarding the rejection of claims 34-36 made by the Examiner under 35 USC 102(e) over Lindqvist et al. (US 6051747) have been fully considered but they are not found persuasive.

5. In regards to the 102(e) rejection, Applicant asserts the following:

**A)** The invention as claimed is structurally distinguishable from the prior art since the foam layer of the reference is not arranged to contact a wound; and

**B)** The claim as amended more particularly distinguishes the invention from the prior art.

6. With respect to assertion A, the Examiner respectfully disagrees. The instant invention is directed to a product and not a method of using the product, i.e. contacting a wound when the contacting side is the side facing the wound (rephrased, see amendment). Determination of

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patentability is based on the product itself. The current amendment is an intended use for how the product is to be used. However, this does not materially affect the product itself. The instant invention is directed to a wound dressing comprising 1) a membrane layer and 2) a foam layer. The Examiner points out that the prior art discloses a foam layer that is not occluded. Figure 2 teaches a foam layer attached directly to a composite gel layer. It is noted that the gel layer 3' does not close, but only covers, a part of the walls in an end portion of the pores of the foam material that face the wound. See column 2, lines 50-53. Thus, the foam does have a wound-contacting surface since the gel layer or adhesive layer does not cover the entire surface of the foam layer. Therefore, Lindqvist's structure and the instant invention as claimed are not structurally distinguishable and the prior art's wound dressing is capable of performing the recited intended use meaning Lindqvist's wound dressing is capable of being used as instantly suggested. Again the Examiner points out that the claimed intended use of the dressing does not impart a structural difference since the prior art may also be turned upside down since it has a foam layer and a membrane layer.

7. In response to B, the Examiner disagrees. Again, the amendments provide how the sides are to be used. The amendment does not provide any new structural feature which distinguishes the instant composite from that of the prior art. As was pointed out under A, Figure 2 of Lindqvist provides a composite structure comprising 1) a membrane layer and 2) a foam layer. As such, the structure anticipates that which is instantly being claimed.

8. Applicants arguments filed 06/01/2009 regarding the rejection of claims 34, 36, 40 and 45 made by the Examiner under 35 USC 102(b) over Hofeditz et al. (US 4552138) have been fully considered but they are not found persuasive.

9. In regards to the 102(b) rejection, Applicant asserts the following:

**C)** The invention as claimed is structurally distinguishable from the prior art since the foam and gel layers of the reference are not arranged to contact a wound; and

**D)** the covering layer is not disclosed to be the foam layer but rather a layer that covers the surface of the gel.

10. With respect to assertion C, the Examiner respectfully disagrees. First, the instant invention is directed to a product and not a method of using the product, i.e. contacting a wound when the contacting side is the side facing the wound (rephrased, see amendment). The instant invention is directed to a wound dressing comprising 1) a membrane layer and 2) a foam layer. Hofeditz discloses a 1) a gel layer that reads on the membrane layer since a membrane is defined as a “thin, soft pliable sheet or layer” and 2) a polyurethane foam layer. See Examples 5 and 6. The membrane layer and the foam layer are both capable of contacting a wound surface. The current amendment is an intended use for how the product is to be used which does not structurally limit the product. The teaching of Hofeditz still anticipates the instant claims.

11. With respect to assertion D, Applicant is directed to Examples 5 and 6. The Examples clearly disclose a membrane layer being laminated ‘with an open-pore foam of polyurethane’. Thus, the resultant structure being 1) a membrane and 2) a foam layer. Applicants arguments are not found persuasive.

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12. Applicants arguments filed 06/01/2009 regarding the rejection of claims 34-36, 38, 42, 43 and 45 made by the Examiner under 35 USC 102(b) over Freeman (US 5681579) have been fully considered but they are not found persuasive.

13. In regards to the 102(b) rejection, Applicant asserts the following:

**E)** The invention as claimed is structurally distinguishable from the prior art since the foam layer of the reference is not arranged to contact a wound, rather the adhesive contacts the wound; and

**F)** Freemans membrane layer is 0.5 to 3 mm thick, where as Applicant is 50 microns as in Example 1.

14. With respect to assertion E, the Examiner respectfully disagrees. The instant invention is directed to a product and not a method of using the product, i.e. contacting a wound when the contacting side is the side facing the wound (rephrased, see amendment). The instant invention is directed to a wound dressing comprising 1) a membrane layer; 2) an adhesive layer; and 3) a foam layer. Hofeditz discloses a 1) a gel layer that reads on the membrane layer since a membrane is defined as a "thin, soft pliable sheet or layer"; 2) an adhesive; and 3) a polyurethane foam layer. See Figures. The foam and the membrane layer are both capable of contacting a wound surface. It's noted that the underside of the foam layer contains an adhesive, but this does not mitigate the instant rejection because the structure of the prior art is identical to that currently being claimed. The current amendment is an intended use for how the product is to be used and does not materially affect the product. The teaching of Freeman still anticipates the instant claims.

15. In response to F, this is not persuasive. The Examiner has rejected the instant claims based on how they read, not on what the specification suggests. If Applicant wishes to distinguish their invention by claiming a thickness for the individual layer(s), then they should do so.

16. Applicants arguments filed 06/01/2009 regarding the rejection of claims 37 and 39-42 made by the Examiner under 35 USC 103(a) over Lindqvist et al in view of Lorenz et al (US 5258421), evidenced by US 4832009 have been fully considered but they are not found persuasive.

17. In regards to the 103(a) rejection, Applicant asserts the following:

**G)** It would not have been obvious to one of ordinary skill to use IPN, and even if it were, then there is potential to have two silicone layers, not a polyurethane foam layer.

18. With respect to assertion G, the premise of the rejection is Lorenz provides the motivation to substitute Lindqvist's polyurethane film with the instant IPN film by teaching both as functionally equivalent. Moreover, one would have been motivated to use IPN over polyurethane because of its advantages such as locking moisture in, preventing bacteria from entering the wound and absorbing excess extrudate to accelerate the healing process. In response to the argument that using IPN could lead to a composite with two silicone layers, this is not persuasive. While it could be possible, the structure of Lindqvist requires that the composite comprise a gel and a foam layer. The foam is that of a polyurethane, and the membrane layer is that of a silicone based polymer. It's important to point out that Lorenz teaches that the polyurethane and IPN are to be used as a membrane, rather than a foam. Thus, one would not

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substitute the foam of Lindqvist for a foam, because Lindqvists structure specifically requires the composite require such.

19. Applicants arguments filed 06/01/2009 regarding the rejection of claim 44 made by the Examiner under 35 USC 103(a) over Lindqvist et al and Freeman have been fully considered but they are not found persuasive.

20. In regards to the 103(a) rejection, Applicant asserts the following:

**H** It would not have been obvious to arrive at an invention where the membrane layer is 50 microns thick.

21. With respect to assertion H, the Examiner respectfully disagrees. As noted in the office action, Lindqvist teaches the foam layer as having a thickness of 1000 microns to 10,000 microns and the polyurethane layer as having a thickness of 25 microns. However, Freeman cures this deficiency as teaching a membrane layer having a thickness between 35 and 76 microns. Therefore, one of ordinary skill would readily be capable of combining the two teachings with a reasonable expectation for arriving at product having the instantly claimed properties.

22. Applicants arguments filed 06/01/2009 regarding the rejection of claims 37 and 39-41 made by the Examiner under 35 USC 103(a) over Freeman in view of Lorenz evidenced by US 4832009 have been fully considered but they are not found persuasive.

23. In regards to the 103(a) rejection, Applicant asserts the following:

**I** It would not have been obvious to one of ordinary skill to use IPN, and even if it were, then there is potential to have two silicone layers, not a polyurethane foam layer.



24. With respect to assertion I, the premise of the rejection is Lorenz provides the motivation to substitute Freemans polyurethane film with the instant IPN film by teaching both as functionally equivalent. Moreover, one would have been motivated to use IPN over polyurethane because of its advantages such as locking moisture in, preventing bacteria from entering the wound and absorbing excess extrudate to accelerate the healing process. In response to the argument that using IPN could lead to a composite comprising a gel and a foam layer, this is not persuasive. The foam is that of a polyurethane, and the membrane layer is that of a silicone based polymer. It's important to point out that Lorenz teaches that the polyurethane and IPN are to be used as a membrane, rather than a foam. Thus, one would not substitute the foam of Freemans for a gel because the references structure specifically requires such.

**Maintained Rejections, of Record**  
***Claim Rejections - 35 USC § 102***

25. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

**26. Claims 34-36 and 45 are rejected under 35 U.S.C. 102(e) as being anticipated by Lindqvist et al (6,051,747).**

27. Lindqvist et al disclose a wound dressing a gel layer (3), which is reticulated into a polyurethane foam layer (2) with open cells (fenestrations) and a thickness of 1-10mm (1000microns to 10,000 microns), and a liquid impervious layer made of a polyurethane film (5).

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See Figures. The gel layer 3 does not close, but only covers, a part of the walls in an end portion of the pores of the foam material that face the wound, excess wound fluid can be drawn into the foam material 2 and absorbed thereby. The polyurethane film is glued to the foam layer. See column 5, lines 63-65. The polyurethane film has high vapor permeability and a thickness of 0.025 mm (25 microns). See column 5, lines 63-65. Note that the polyurethane film in this embodiment read on the instant membrane layer since “membrane” is defined as “a thin sheet of natural or synthetic material”. Note also in this embodiment the glue reads on the adhesive layer since the glue acts to bond the foam and the film.

28. With regard to lines 4-9 of independent claim 34, it is the examiner’s position that since Lindqvist discloses a wound dressing that is multi-layered wherein the two layers are different, i.e. made of different material; thus the would dressing is capable of meeting the intended use recited in lines 4-9. The examiner points out that the instant invention and the prior art are not structurally distinguishable and thus the prior art is capable of performing the recited intended use.

29. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

**30. Claims 34, 36, 40, and 45 are rejected under 35 U.S.C. 102(b) as being anticipated by Hofeditz et al (4,552,138).**

31. Hofeditz et al disclose a dressing material comprising at least one layer of hydrophilic, transparent polymeric gel (see column 2, lines 44-45) and a carrier material. Example 5

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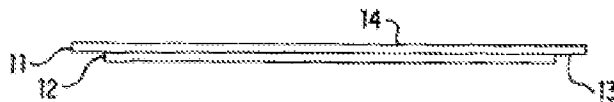
discloses the gel layer laminated to an open-pore (fenestrations) polyurethane foam. Hofeditz discloses the additional use of dyes and pigments. See claim 13 and examples.

32. It should be noted that membrane is defined as a “thin, soft pliable sheet or layer”; thus Hofeditz polymeric gel layer reads on “membrane layer”.

33. With regard to lines 4-9 of independent claim 34, it is the examiner’s position that since Hofeditz discloses a wound dressing that is multi-layered wherein the two layers are different, i.e. made of different material; thus the would dressing is capable of meeting the intended use recited in lines 4-9. The examiner points out that the instant invention and the prior art are not structurally distinguishable and thus the prior art is capable of performing the recited intended use.

**34. Claims 34-36, 38, 42-43, and 45 are rejected under 35 U.S.C. 102(b) as being anticipated by Freeman (5,681,579).**

35. Freeman discloses a polymeric support wound dressing. See abstract. Figure 1 discloses the occlusive layer (11) (second layer) bonded by adhesives (13) means to a hydrocolloid containing polymeric layer (12) (first layer).



The occlusive layer 11 has an upper or outer surface 14, which is open to the atmosphere and an inner surface 13, which is the side toward the skin. The occlusive layer is preferably a polyurethane foam. See column 4, lines 30-31. The adhesive layer may for example extend across the entire under surface 13 of the occlusive layer or only a portion of it. The polymeric support layer 12 is any polymeric material useful in medical settings and is in the form of a web, net, perforated film or perforated layer. The polymeric support layer 12 contains a hydrocolloid either blended with the polymeric material. When the hydrocolloid is blended with the polymeric material it is preferred that the two materials be extruded together to form a film. See column 5, lines 1-30. It should be noted that a membrane is defined as a “thin, soft pliable sheet or layer”; thus Freeman’s polymeric support reads on instantly claimed “membrane layer”. The polymeric support layer is

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0.5-3 mils (35 microns to 76 microns). See column 4, lines 5-8. The adhesive layer is made of various substances including silicone rubber. See column 6, line 31.

36. Dressing A discloses a hydrocolloid centered on polyurethane foam, which is adhered to a perforated polyurethane perforated film. See column 10, lines 20-45.

37. With regard to lines 4-9 of independent claim 34, it is the examiner's position that since the prior art discloses a wound dressing that is multi-layered wherein the two layers are different, i.e. made of different material; thus the would dressing is capable of meeting the intended use recited in lines 4-9. The examiner points out that the instant invention and the prior art are not structurally distinguishable and thus the prior art is capable of performing the recited intended use. Moreover, a portion of layer 11, the foam, along with layer 12, contacts the skin surface as disclosed by Freeman on column 4, lines 13-15.

***Claim Rejections - 35 USC § 103***

38. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

**39. Claims 37 and 39-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lindqvist et al (6,015,747) in view of Lorenz et al (5,258,421) and as evidenced by US 4832009.**

40. The disclosure of Lindqvist has been set forth above.

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41. Lindqvist does not teach the use of instant silicone-polytetrafluoroethylene IPN membrane layer. Further, the addition of a pigment is not taught.

42. Lorenz et al teaches a hydrophilic gel dressing (Note abstract). The dressing is made of a tacky gel of polyurethane and poly (N-vinyl lactam) on a substrate. Lorenz teaches coating the gel layer on a backing substrate. The backing substrate provides liquid barrier properties and may be a polymer film such as polyurethane film or silicone-polytetrafluoroethylene IPN membrane film. Lorenz teaches silicone-polytetrafluoroethylene has particular utility in wound dressing because it keeps moisture in and excess exudate is absorbed to promote healing. See column 5, lines 50-68. When the backing substrate is of the instant silicone-polytetrafluoroethylene, the structure is also useful as a burn blanket. See 5, lines 30-33 and column 6, lines 28-30. Additionally, Lorenz teaches the use of various conventional additives such as pigments and dyes in the gels. See column 4, lines 49-55. It should be noted that IPN is implicitly translucent.

43. It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Lindqvist et al and Lorenz et al and replace Lindqvist's polyurethane polymer film with the instant silicone-polytetrafluoroethylene IPN polymer film. One would have been motivated to do so since Lorenz teaches that both polyurethane films and the instant film have Liquid barrier properties; however the instant IPN polymer film provides certain advantages for wound and burn dressing by keeping the moisture in, preventing bacteria from entering the wound and absorbing the excess exudates, thereby promoting healing. Therefore, a skilled artisan would have been motivated to utilize the instant polymer film (IPN) in Lindqvist's wound dressing over Lindqvist's polyurethane film for the advantages taught by

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Lorenz, i.e. if one desired to provide a structure that also promoted healing by preventing re-infection, i.e. by preventing bacteria from entering the wound site. A skilled artisan would have reasonably expected success and similar results since Lorenz teaches both Lindqvist's polyurethane film and instant silicone-polytetrafluoroethylene IPN function in a similar manner, i.e. functional equivalents (both are liquid impervious layers that are utilized in wound dressing).

44. With regard to claim 40, it would have been obvious to add a pigment to Lindqvist's gel if one desired for an article with a gel layer with a distinct layer. It should be noted that the instantly claimed aesthetic design change does not impart patentable significance with regard to the mechanism in which the wound article functions.

45. With regard to claim 41, it is noted that polymeric film layers are implicitly translucent unless a pigment is added. Further, it should be noted that US '009 substantiates the examiner's position that the silicone-polytetrafluoroethylene IPN are transparent. Note column 1, lines 55-60 of US '009. Thus, thus reads on "substantially transparent". Further, polyurethane foams are implicitly opaque. With regard to the addition of pigment to the adhesive layer, it is considered prima facie obvious to add a pigment to any layer to distinguish each layer. It should be noted that the instantly claimed aesthetic design change does not impart patentable significance with regard to the mechanism in which the wound article functions.

46. With regard to claim 42, pores (fenestrations) are a property of silicone-polytetrafluoroethylene IPN films. US '009 substantiates this. Note column 1, lines 45-60 of US '009.

**47. Claim 44 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lindqvist et al (6,015,747) by itself or in view of Freeman (5,681,579).**

48. The disclosure of Lindqvist has been set forth above. The reference teaches the foam has a thickness of 1-10mm (1000microns to 10,000 microns), and a liquid impervious layer (polyurethane film) has a thickness of 0.025 mm (25 microns).

49. Lindqvist does not teach the instant thickness of the membrane layer, i.e. 50 microns.

50. Freeman teaches a polymeric support wound dressing, which comprises a occlusive layer and a support layer. See abstract. Figure 1 discloses the occlusive layer (11) (second layer) is preferably a polyurethane foam bonded by adhesives (adhesive layer) means to a perforated film (12) (first layer). See also column 4 to column 5 and examples. Dressing A discloses a hydrocolloid centered on a polyurethane foam, which is adhered to a perforated polyurethane perforated film. See column 10, lines 20-45. The polymeric support layer is 0.5-3 mils (35 microns to 76 microns). See column 4, lines 5-8.

51. It would have been obvious to one of ordinary skill in the art at the time the invention was made to look to the guidance provided by Lindqvist and manipulate the thickness of the liquid impervious layer from 25 microns to 50 microns. One would have been motivated to manipulate the thickness of this layer since the polymeric layer functions to support the foam layer. Thus, depending on factors such as the weight and thickness of the foam layer one would have been motivated to utilize the appropriate thickness to support the foam layer and provide strength to the entire structure.

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52. Further, it would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Lindqvist and Freeman and manipulate the thickness of the liquid impervious layer from 25 microns to 50 microns. One would have been motivated to do so since Freeman teaches polyurethane films may be in a thickness of 35-76 microns. Therefore, a skilled artisan would have been motivated to manipulate the thickness of this layer since the polymeric layer functions to support the foam layer. Thus, depending on factors such as the weight and thickness of the foam layer one would have been motivated to utilize the appropriate thickness to support the foam layer and provide strength to the entire structure.

**53. Claims 37, 39-41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Freeman (5,681,579) in view of Lorenz et al (5,258,421) and as evidenced by US 4832009.**

54. The disclosure of Freeman has been set forth above.

55. Freeman does not teach the use of instant silicone-polytetrafluoroethylene IPN membrane layer or a pigment.

56. Lorenz et al teaches a hydrophilic gel dressing (Note abstract). The dressing is made of a tacky gel of polyurethane and poly (N-vinyl lactam) on a substrate. Lorenz teaches coating the gel layer on a backing substrate that provides liquid barrier properties and may be a polymer film such as polyurethane. The polymer film may also be silicone-polytetrafluoroethylene IPN membrane. Lorenz teaches silicone-polytetrafluoroethylene has particular utility in wound dressing because it keeps moisture in and excess exudate is absorbed to promote healing. See



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column 5, lines 50-68. When the backing substrate is of the instant silicone-polytetrafluoroethylene, the structure is also useful as a burn blanket. See 5, lines 30-33 and column 6, lines 28-30. Additionally, the backing substrate may be covered by a silicone-coated release-liner. Additionally, Lorenz teaches the use of various conventional additives such as pigments and dyes in the gels. See column 4, lines 49-55. It should be noted that IPN is implicitly translucent.

57. It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Freeman et al and Lorenz et al and replace Freeman's polyurethane polymer film with the instant silicone-polytetrafluoroethylene IPN polymer film. One would have been motivated to do so since Lorenz teaches that both polyurethane films and the instant film have Liquid barrier properties; however the instant IPN polymer film provides certain advantages for wound and burn dressing by keeping the moisture in, preventing bacteria from entering the wound and absorbing the excess exudates, thereby promoting healing. Therefore, a skilled artisan would have been motivated to utilize the instant polymer film (IPN) in the wound dressing over Freeman's polyurethane film for the advantages taught by Lorenz, i.e. if one desired to provide a structure that also promoted healing by preventing re-infection, i.e. by preventing bacteria from entering the wound site.

58. With regard to claim 40, it would have been obvious to add a pigment to the gel if one desired for an article with a gel layer with a distinct layer. It should be noted that the instantly claimed aesthetic design change does not impart patentable significance with regard to the mechanism in which the wound article functions.

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59. With regard to claim 41, it is noted that polymeric film layers are implicitly translucent unless a pigment is added. Further, it should be noted that US '009 substantiates the examiner's position that the silicone-polytetrafluoroethylene IPN are transparent. Note column 1, lines 55-60 of US '009. Thus, thus reads on "substantially transparent". Further, polyurethane foams are implicitly opaque. With regard to the addition of pigment to the adhesive layer, it is considered prima facie obvious to add a pigment to any layer to distinguish each layer. It should be noted that the instantly claimed aesthetic design change does not impart patentable significance with regard to the mechanism in which the wound article functions.

### ***Conclusion***

1. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

2. A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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3. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kyle A. Purdy whose telephone number is 571-270-3504. The examiner can normally be reached from 9AM to 5PM.

4. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila Landau, can be reached on 571-272-0614. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

5. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

*/Kyle Purdy/  
Examiner, Art Unit 1611  
September 10, 2009*

*/David J Blanchard/  
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